Baird, Annette M.

From: Copple, Carol B.
Sent: Tuesday, November 26, 2002 9:11 AM
To: Copple, Carol B.; Griffin, William T.; Elves, Robert G.
Cc: Angel, Jan A; Roethig, Hans; Patskan, George J.; Davies, Bonnie J.
Subject: RE: APE for Accord (JLI)

I have tried to recall the message I sent to you yesterday at 10:36. The case log was mistakenly identified as being on Accord. It was actually on SCoR. I apologize for the confusion. Following is the case log on the only APE complaint the CRC has received on Accord this year.
Carol

Contact Management System | CASE LOG | Date Log Created: 11-26-2002

Philip Morris USA | Bettie Nelson | Time Log Created: 09:04:53

Case Information

Number: 1090145 | Last Updated On: 30-JUL-02 | Case Status: Closed
Case Created On: 28-JUN-02 | Last Updated By: copplec
Case Created By: copplec | Closed On:30-JUL-02
Case Owner: copplec
Case Assigned To Owner On: 6/28/02

Contact Information

Created By: copplec
On: 28-JUN-02

Consumer: Bettie Nelson

Gender: Birth Date:
Do Not Contact: N No Mail: N
Do Not Contact By Phone: N
Home Phone:
Office Phone: 402 476-2811 Ext.
Fax Phone: 402
Alternate Phone: 402 476-4941 Ext.

Issue

Complaints, No Presenting Cause, No Presenting Cause, No Presenting Cause
Accord, Ultra Lights, Other Size, Hard Pack, Regular, Filtered

Created By: copplec
On: 28-JUN-02

Purchase Information
Quantity: Affected Quantity:

Last Updated By: colesj
On: 23-JUL-02

Manufacturing Information
Cold Storage: N Factory Smoke: N

Issue Note

Created By: 07/22/02 03:51:21 PM
On: 22-JUL-02

Note Type: Product Integrity
Per memo from R. Elves and D. Compton, A. Jerome can close this type of request.(no difference)

Issue Note

Source: https://www.industrydocuments.ucsf.edu/docs/tlhk0001

Created By: 07/23/02 11:31:56 AM
On: 23-JUL-02

Note Type: Investigator
Sending complaint return to Sue Wrenn at Ashland; chain of custody form signed and attached.

Case Note

Created By: copplec Method: Telephone - Inbound
On: 06/28/02 05:14:33 PM Tone:

Note Type: Investigator
This complaint was escalated from the EHCSS Call Center in Richmond. The following information was received via fax: Alleged Complaint, Level 1, occurred during the WSA study in Lincoln, NB: Facility Phone Number 402-476-2811 or 4941 Betty Nelson, WSA and Magan McCury, nurse at the MDS facility in Lincoln, NB, telephoned Bonnie Davies to pass on an alleged physical complaint (level 1). The MDS Nurse, Magan McCury discussed the following information:

The study participant (Lincoln's identification participant #17, PJC) has experienced small, red, raised bumps that began on the trunk of her body and are spreading to her neck, arms, legs, and head. Participant also gave a description of a "bleachey taste from the cigarettes." No itching from the red bumps. She was seen by Dr. Kisicki (Dr. at MDS facility) who decided that there was a possibility that the rash could be related to the Accord Smoking System. The Dr. instructed her to take 25 mg of Benedryl every 6 hours. Per Betty Nelson's decision, the subject will remain on study, but will be given the choice of a completely new smoking system and cigarettes. Her old smoking system and unsmoked cigarettes will be returned to Philip Morris for analysis. Magan McCury (Nurse) has spoken with the study participant and she is willing to do a check in tonight (6-28-02). The study participant has also been instructed to call MDS if any more problems arise.

-----Original Message-----
From: Copple, Carol B.
Sent: Monday, November 25, 2002 9:51 AM
To: Griffin, William T.; Elves, Robert G.
Cc: Angel, Jan A; Roethig, Hans; Patskan, George J.; Davies, Bonnie J.
Subject: RE: APE for Accord (JLI)

Robbie,
The JLI APE is the only one I have seen. Bonnie Davies manages the call center for Accord--I am copying her on this as an FYI. Their call center's procedures call for forwarding all APEs to the Consumer Response Center.
Carol

-----Original Message-----
From: Griffin, William T.
Sent: Friday, November 22, 2002 2:26 PM
To: Elves, Robert G.; Copple, Carol B.
Cc: Angel, Jan A; Roethig, Hans; Patskan, George J.
Subject: RE: APE for Accord (JLI)

The only JLI APE was the one listed in the original email. There was also an APE for E4. I can provide the details for that if needed.
Bill

-----Original Message-----
From: Elves, Robert G.
Sent: Friday, November 22, 2002 11:24 AM
To: Copple, Carol B.; Griffin, William T.
Cc: Angel, Jan A; Roethig, Hans; Patskan, George J.
Subject: APE for Accord (JLI)

Carol/Bill - In preparation for our next SAB, we would like to provide to the SAB the status of any reported alleged physical effects (APE) associated with the Accord (JLI). To my knowledge we have had only one APE, this coming from the long term JLI clinical study and it was resolved as unrelated transient viral infection. Please confirm this reported APE along with any others that have come in through either of our call centers so that we may provide an update to the SAB. Please cc: George in your response. Thanks. - Robbie

Source: https://www.industrydocuments.ucsf.edu/docs/tlhk0001

Cc: Milby, Colleen B.; Dierkes, Jo S.; Bugg, Joy J.; Whetzal, Mary Alice; Townsend, Sue V.; Baird, Annette M.; Cannon, Eleanor H.; Casella, Judy; Grau, Marta S.; Gunn, Betsy; Jones, Carolyn R.; Washington, Pamela; Russ, Janice W.; Shade, Charlene R.
Subject: REVISED AGENDA - RD&E STAFF - DECEMBER 6

Please find attached the revised agenda for the RD&E Staff Meeting for Friday, December 6 - OBT Conference Room.

<< File: RDE_Agenda Dec6.doc >>

Thanks,
Sue

Baird, Annette M.

From: PMI, Corporate Affairs
Sent: Tuesday, November 26, 2002 5:33 AM
Subject: PMIeNews - 26 November

Please find below today's PMI *eNews*:

PMIeNews - 26 November.doc

For more news, please go to: http://enews.us.pm.com/pmi/main.asp

Best regards,
Your Internal Communications Team

Baird, Annette M.

From: Tricker, Anthony
Sent: Tuesday, November 26, 2002 4:11 AM
To: Roethig, Hans; Sarkar, Mohamadi; Kinser, Robin D.; Schorp, Matthias; Dempsey, Ruth; Takada, Kohji; Major, Tamas; Patskan, George J.; Haussmann, Hans-Juergen; Roemer, Ewald; Tewes, Franz; Podraza, Ken F.
Cc: Solana, Rick P.; Reininghaus, Wolf; Sanders, Edward; Tricker, Anthony
Subject: More on urinary mutagenicity

Please find the attached abstract entitled "Tobacco-smoke exposure indictors and urinary mutagenicity" by Pavanello et al. Reference is made to urinary 1-pyrenol, this is another name for 1-hydroxypyrene.

Entrez-PubMed.htm

PM3001128964

Source: https://www.industrydocuments.ucsf.edu/docs/tlhk0001